IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff	)	
	)	
-VS-	)	Criminal No. 15-10076-ADB
	)	
WILLIAM FACTEAU and	)	
PATRICK FABIAN,	)	
	)	
Defendants	)	

JURY INSTRUCTIONS PART II
July 15, 2016

BEFORE THE HONORABLE ALLISON D. BURROUGHS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 17
Boston, Massachusetts 02210

KELLY MORTELLITE, RMR, CRR
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 5200
Boston, MA 02210

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P R O C E E D I N G S

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THE COURT: I'm in the homestretch here. All that's left is my charge, and the case will be yours. The charge is my opportunity to educate you about the law that you need to apply to the facts as you find them, so you can imagine in this case it's dense and it's complicated. Because you've only been sitting for an hour at this point, I'm going to start the charge, do the first slug of it, and then give you your break just so you don't end up sitting too long all at one time.

02:03

You've heard the first portion of the charge. That doesn't mean it's the most important part of it. You're going to hear the last part of it today. That doesn't mean that's the most important part of it. It is all equally important. We're just trying to split it up to make it digestible to give you a reasonable schedule. So it is all important.

So as I said, I'm going to do one slug now, give you a break, and then finish it off. Now I turn to the indictment in this case and the statutes on which it is based.

02:04

First, I remind you that an indictment is not evidence of any kind against the defendants. The indictment is just an accusation filed in writing with the Court to bring a criminal charge against a defendant. As you've heard, the indictment in this case has 14 counts. Count 1 charges both defendants with conspiring to commit violations of the Federal Food, Drug and

Cosmetic Act, which makes it unlawful to introduce or cause the introduction of adulterated and/or misbranded medical devices in interstate commerce.

Counts 5 through 7 charge both defendants with wire fraud. That is participating in a fraudulent scheme to distribute the Stratus for an intended use not cleared or approved by the FDA and concealing the conduct all to increase the valuation and revenues of Acclarent and using specific e-mails or wire transmissions in furtherance of the scheme.

02:05 Counts 9 through 18 charge both defendants with substantive violations of the Federal Food, Drug and Cosmetic Act based on the allegation that they introduced or caused the introduction of a misbranded and/or adulterated device in interstate commerce and that they did so with the intent to fraud or mislead.

As we discussed at the outset, there are gaps in numerical sequence. If I did not mention a count, that is because there is no count with that number in this case. Missing counts are not relevant to your deliberations and you

02:05 should draw no conclusions from the numbering.

Both defendants deny that they are guilty of these charged offenses and are presumed to be innocent. Again, if you find a defendant guilty, the government must prove each element of a charged offense beyond a reasonable doubt.

I'm now going to talk to you about the provisions of

the Federal Food, Drug and Cosmetic Act, also referred to as the FDCA, that will be relevant to your consideration of the charges in this case. The FDCA requires that most new medical devices, unless exempted, be approved or cleared by the Food and Drug Administration, or FDA, before they can be introduced in interstate commerce. The FDCA also prohibits the introduction into interstate commerce of misbranded and adulterated medical devices.

The FDCA classifies medical devices according to the risks associated with their use. There are three classes that can be assigned to a device -- Class I, Class II or Class III. Each class is subject to different regulatory controls with Class I devices getting the least scrutiny and Class III devices getting the most. Device classification depends on the technology and the intended use of a device. Thus, a single device can be assigned to different classes based on different intended uses, and similarly, two devices that are otherwise the same can be assigned to different classes based on different intended uses.

Any device that was not distributed before May 28, 1976, is automatically classified as a Class III device unless that device has otherwise been classified by the FDA as a Class I or Class II device. The government and the defendants have stipulated, that is agreed, that the Stratus was not introduced into interstate commerce prior to May 1976.

A device classified as a Class III device must be approved by the FDA before it can be distributed in interstate commerce. This is generally accomplished through the Premarket Approval, also called the PMA, process, which involves the manufacturer of the device submitting a premarket approval application to the FDA. Once a manufacturer of a Class III device has submitted a premarket approval application to the FDA, the FDA will approve the PMA for the device only if the information in the PMA provides the FDA with reasonable assurance that the device is safe and effective under the conditions of use recommended in the device's proposed labeling.

A device can be removed from the automatic Class III designation, bypass the PMA process, and be assigned to either Class I or Class II if the manufacturer obtains a Section 510(k) determination or order of "substantial equivalence" from the FDA for the device's intended use. "Substantial equivalence" means that the device has the same intended use as the predicate device and the FDA has found that the device has the same intended use as an already cleared Class I or Class II "predicate" device, and, in addition, that (1) it has the same technological characteristics of the predicate device, or, (2) if the technological device's characteristics are different, that the device is at least as safe and effective as the predicate device and does not raise different questions of

either safety or effectiveness than the predicate device.

A manufacturer seeking to obtain a determination of substantial equivalence for a new device must submit a premarket notification, also referred to as a "510(k) submission," to the FDA at least ninety days before the manufacturer intends to start commercially distributing the device.

"Intended use" is a defined term under the FDCA and its regulations, meaning that it doesn't necessarily have what you might think of as its usual, everyday meaning. During the 510(k) review process of the FDA's determination of whether a new device's intended use is the same as the predicate device's intended use is based solely on the manufacturer's proposed labeling for the new device, which must be part of the 510(k) submission. A manufacturer's submission of labeling and its statement in intended use in the 510(k) notification means that that is the intended use for which the manufacturer seeks clearance under section 510(k). The manufacturer is not required to submit all possible or contemplated uses of the device in its 510(k) notification.

When determining that a device is substantially equivalent to a legally marketed device, the FDA may require a statement in the labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if the FDA determines and states in writing (1) that

there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and (2) that such use could harm.

If the FDA issues a "substantial equivalence" order for a device, the manufacturer may then market the device for the intended use described in the 510(k) submission.

A device that is cleared by the FDA may be legally used by physicians for uses other than the use for which it is cleared or approved. This is referred to as off-label use. Physicians are legally permitted to use a cleared or approved device for any purpose including an off-label purpose. Off-label use is common. A device cleared under the 510(k) process is not adulterated or misbranded merely because a physician uses the device for an off-label purpose.

Although the FDA and FDCA regulate the marketing of medical devices, they do not regulate the practice of medicine or how physicians use medical devices, nor do they limit the authority of doctors to use medical devices that have been approved or cleared for one use for a different, unapproved, or uncleared use. The FDA does, however, regulate manufacturers in their distribution of medical devices by prohibiting them from distributing medical devices for any intended use that has not been FDA-cleared or approved.

Merely distributing a device with knowledge that it will be used for a use other than the use cleared or approved

by the FDA is not fraudulent or illegal. That being said, if a manufacturer has received 510(k) clearance to distribute a device for one intended use, it may not distribute the device for a significantly different intended use unless it obtains a new 510(k) clearance or a PMA approval for the device with that new intended use. I will explain what is meant by "intended use" in the distribution context a bit later in these instructions.

Off-label promotion refers to promoting a device for an off-label use, meaning an intended use that has not been FDA-cleared or approved. It is not illegal in and of itself for a device manufacturer to provide truthful, not misleading information about an off-label use. The FDCA does not prohibit or criminalize truthful, not misleading off-label promotion. You may not convict the defendant of a crime based solely on truthful, non-misleading statements promoting FDA-cleared or approved device, even if the use being promoted is not a cleared or approved use. Over the course of this trial you've heard evidence about a number of statements, marketing claims, and other communications about the Stratus. It is up to you to decide whether a statement is truthful and non-misleading or whether it is false and misleading.

The indictment in this case does not charge any defendant with the crime of promoting a device off-label, because that is not itself a crime. Rather, the FDCA crimes

charged are conspiring to introduce and causing the introduction of devices in interstate commerce that were adulterated or misbranded. Although you may not convict a defendant of a crime based solely on truthful, non-misleading statements regarding off-label use, even truthful statements about an off-label use can be considered as evidence. To put it another way, to convict there must be a criminal act. Truthful, non-misleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to
02:12 determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent.

As I have mentioned, "intended use" is a defined legal term. I have previously instructed you on the meaning of "intended use" during the FDA's 510(k) clearance process. I now will instruct you on the meaning of "intended use" as it applies outside the clearance process.

The term "intended use" refers to the objective intent of the manufacturer or seller of the device. The intent is
02:13 determined by such person's expression or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the device is, with the knowledge of such

persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. A device can have more than one intended use.

Mere knowledge that doctors are using a device for purposes other than its labeled use does not give rise to a new intended use. Off-label promotional statements can constitute evidence of an intended use, although truthful, non-misleading speech alone cannot be the basis for a criminal conviction. Neither the First Amendment nor any other law, however, protects false or misleading speech.

In addition, it is permissible to respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading and non-promotional scientific or medical information that is responsive to the specific request, even if responding to the request requires a manufacturer to provide information on unapproved or uncleared indications or conditions of use. Under these circumstances, such responses may not be considered as evidence of a new or different "intended use."

The term "label" and "labeling" have specific meanings under the FDCA. "Label" means any written, printed or graphic matter upon the immediate container of a product. All words, statements and other information required to be on the label must also appear on the outside container or wrapper.

"Labeling" is broader than the term "label." "Labeling" means all labels, as well as any other written, printed, or graphic matter on or accompanying the product in interstate commerce. Labeling may include promotional material or literature, including package inserts, pamphlets, mailing pieces, fax bulletins, reprints of press releases, information posted on internet websites selling the product, and all of the literature from the manufacturer that supplements or explains the product in connection with its sale.

02:15 Okay. That largely concludes my instructions on the FDCA. We'll come back and focus on the specific elements of the specific charges after you take a 15-minute break. And I may give you a little longer. So around 2:25, 2:30, okay?

(Recess taken.)

THE COURT: All right. I'm going to conclude the instructions, but first I want to give you one additional instruction in response to closing arguments today.

I want to reiterate that the burden of proof is always on the government. The defendant has no obligation to call any

02:41 witnesses. I further instruct you that only the government has the ability to immunize witnesses. An unimmunized witness may, for all practical purposes, be unavailable to testify.

All right. I'm going to finish up the charge now. Now I'm going to give you some more specific instructions on crimes charged in the indictment and the elements of the

offenses that the government must prove beyond a reasonable doubt. I will explain each of the charges alleged in the 14 counts, although I am not going to do it in numerical order.

Having just discussed the Food, Drug and Cosmetic Act, I'm going to begin with the adulteration and misbranding charges (Counts 9 through 18) and then move on to Count 1, which alleges a conspiracy to violate the FDCA, and finally the wire fraud counts, Counts 5 through 7.

Counts 9 through 18 charge the defendant with violations of the Federal Food, Drug and Cosmetic Act, which I've been referring to as the FDCA. Counts 9 through 13 of the indictment charge the defendants with introducing or causing the introduction of an adulterated medical device into interstate commerce, and Counts 14 through 18 of the indictment charge the defendants with introducing or causing introduction of a misbranded medical device in interstate commerce. Each of these charges requires the government to prove three elements beyond a reasonable doubt. For misbranding and adulteration, the first two elements are the same, although the third is different for the two charges. I'm going to begin by instructing you on the two elements that are common to both adulteration and misbranding and finally instruct on the third element that the government must prove beyond a reasonable doubt first for adulteration then for misbranding.

The first element they must prove beyond a reasonable

doubt for both misbranding and adulteration is that the Stratus was a "device" regulated under the FDCA. For purposes of your deliberations, the parties have stipulated that the Stratus is a prescription medical device as those terms are defined in the FDCA. The second element the government must prove beyond a reasonable doubt for both adulteration and misbranding is that the defendant caused the Stratus to be delivered or introduced into interstate commerce. "Interstate commerce" means commerce between any state and any place outside of that state, including other states or a foreign country. With regards to Counts 9 through 13, the indictment alleges the following:

Count 9 concerns a Stratus shipped to Hospital 1 in South Weymouth on approximately October 21, 2009

Count 10 concerns a Stratus shipped to Hospital 2 in Plymouth on approximately November 6, 2009

Count 11, a Stratus shipped to Hospital 3 in Lowell on approximately November 17, 2009

Count 12, a Stratus shipped to Hospital 4 in Hyannis on approximately August 11, 2010

Count 13, a Stratus shipped to Hospital 5 in Worcester on approximately February 25, 2011

With regards to Counts 14 through 18, the indictment alleges the following:

Count 14 concerns a Stratus shipped to Hospital 4 in Hyannis on approximately December 15, 2009

Count 15, a Stratus shipped to Hospital 1 in South Weymouth on approximately January 19, 2010

Count 16, a Stratus shipped to Hospital 2 in Plymouth on approximately January 10, 2010

Count 17, a Stratus shipped to Hospital 1 in South Weymouth on approximately October 13, 2010

Count 18, a Stratus shipped to Hospital 5 in Worcester on approximately May 27, 2011.

The government and the parties -- and the defendants 02:45 have stipulated that the Stratus shipments identified in Counts 1 and 9 through 18 were introduced into and traveled in interstate commerce, but you will still need to determine whether a defendant caused that to happen.

For the crime of introducing or causing the introduction of adulterated devices in interstate commerce charged in Counts 9 through 13 of the indictment, the third element that the government must prove beyond a reasonable doubt is that the Stratus was adulterated.

A medical device is adulterated if it is a Class III 02:45 device that is required to have but does not have an FDA-approved premarket approval or "PMA" application for particular intended use and is not otherwise exempt from such approval.

If a device has been classified by the FDA as a Class I or Class II device under a 510(k) clearance, then it is not a

Class III device for the intended use for which it has been cleared, although it would be a Class III device for any uncleared or unapproved intended use that is significantly different from the use for which it was cleared unless it is Class I exempt. The fact that a physician buys a cleared device in order to use it for an off-label purpose does not change the classification of the device.

In sum, for you to find a defendant guilty of these counts, the adulteration counts, the government must prove each of the following elements beyond a reasonable doubt:

One: That the Stratus products listed in Counts 9 through 13 were "devices;"

Two: That the defendant caused those products to be introduced in interstate commerce;

Three: That those products were adulterated.

Counts 14 through 18 of the indictment charge the defendants with introducing or causing the introduction of a misbranded device in interstate commerce. In order to find the defendant guilty of any of these charges, you must find that the government has proved the following elements beyond a reasonable doubt:

One: That the Stratus products listed in Counts 14 through 18 were "devices;"

Two: That the defendant caused those products to be introduced in interstate commerce and;

Three: That those products were "misbranded."

I defined the terms "device" and "interstate commerce" earlier in these instructions, and they have the same meaning here.

Counts 14 through 18 allege that the Stratus devices were misbranded in three specific ways, which I will discuss in a minute. To find either defendant guilty of introducing or causing the introduction of misbranded devices into interstate commerce, you must find beyond a reasonable doubt that the Stratus devices were misbranded in at least one of these three ways. You do not need to find that the devices were misbranded in more than one way, but you must be unanimous as to which type of misbranding, if any, the government has proven beyond a reasonable doubt.

First, a device is misbranded if its labeling is materially false or misleading in any particular. I instructed you earlier on the definition of "labeling" and you should use that same definition throughout.

In determining whether a device's labeling is misleading, you may take into account, among other things, not only representations made or suggested by statements, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in light of such representations or with respect to such consequences which may result from the use of the device under the

conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. Half truths or incomplete statements that omit material information can make a label false and misleading if the omitted information is necessary to avoid making the statement misleading.

A fact is "material" if it has a natural tendency to influence or is capable of influencing the decision of the decisionmaker to whom it was addressed.

Second, a medical device is also misbranded if the
02:48 manufacturer introduces the device into interstate commerce for an intended use that is significantly different from the use covered by its 510(k) clearance and without submitting a new premarket notification to the FDA regarding the different intended use.

Finally, a device is misbranded if its labeling does not bear adequate directions for its intended use.

"Adequate directions for use" for a prescription device like the Stratus means that any labeling that furnishes or purports to furnish information for the use of the device
02:49 must bear adequate information for such use, including indications, effects, routes, methods and frequency or duration of administration and any relevant hazard, contraindications, side effects and precautions under which practitioners licensed by law to use the device can use it safely and for the purpose for which it is intended, including all purposes for which it

was advertised or represented. This information may be omitted from a package from which the device is to be dispensed, if, but only if, the directions, hazards, warnings, and other information are commonly known by practitioners licensed by law to use the device and there is no labeling on or within the package from which the device is to be dispensed that furnishes or purports to furnish any information for the use of the device.

With regards to Count 9 through 18, you must first
02:49 determine whether the government has proved beyond a reasonable doubt that a defendant caused the introduction into interstate commerce of adulterated or misbranded devices. If you find that a defendant caused the introduction into interstate commerce of adulterated or misbranded devices, you should then consider when the defendant held a "position of responsibility" within Acclarent and the authority to prevent or to correct the adulteration or misbranding violations charged in the indictment. If you find beyond a reasonable doubt that the defendant held such a position of responsibility with respect
02:50 to the adulteration or misbranding counts charged in the indictment but failed to prevent or correct the violations, you may find the defendant guilty of causing introduction of adulterated or misbranded devices into interstate commerce, even if he did not intend the devices to become adulterated or misbranded and did not personally know about the specific

circumstances that caused the devices to become adulterated or misbranded.

A defendant cannot be convicted solely based on his position in the company or if you find it was impossible for him to prevent or correct the adulteration or misbranding charged in the indictment. Rather, the government must prove beyond a reasonable doubt that the defendant had the authority to prevent or correct the specific adulteration or misbranding charged here and that preventing the introduction of misbranded or adulterated devices into interstate commerce was not impossible.

Good faith, which I will discuss in more detail shortly, is not a defense because the law does not require a defendant to know about or to actively have engaged in wrongdoing in order to be held responsible for his company's distribution of adulterated or misbranded devices. All that the law requires is that the defendant held such a position of responsibility within the company and that he had sufficient authority to prevent or correct the violation and that the violation nonetheless occurred or was not corrected.

Again, with regard to Counts 9 through 18, if for a particular count and defendant, you do not find beyond a reasonable doubt that the defendant caused the introduction of adulterated or misbranded devices as charged in that count, you should acquit that defendant on that count and move on to the

next. If, however, you do find beyond a reasonable doubt that a defendant caused the introduction of adulterated and/or misbranded devices into interstate commerce as charged in each of Counts 9 through 18, you must then go on to determine whether the government has also proved beyond a reasonable doubt that the defendant committed the adulteration or misbranding violations with the intent to defraud or mislead. There will be two separate questions that you will have to answer. First, consistent with my instructions, did the
02:52 defendant cause the introduction into interstate commerce of adulterated and/or misbranded devices? If no, then move on to the next count. But if yes, you must then decide if he did so with the intent to defraud or mislead.

A defendant acts with intent to defraud or mislead under the FDCA if the defendant acts with a specific intent to defraud or mislead either the government or individuals.

To act with the intent to defraud or mislead, the government means to act with the specific intent to interfere with or obstruct a lawful government function by deceit, craft,
02:53 trickery or dishonesty ordinarily for the purpose of either causing some financial loss to another or bringing about some financial gain to the defendant or another. The government must prove beyond a reasonable doubt that there was an intent to defraud or mislead an identifiable regulatory agency rather than just a general intent to defraud or mislead. An intent to

defraud or mislead the government can be demonstrated through evidence that the defendant took steps, in connection with the distribution of products, to conceal material facts from the FDA or that a defendant acted with an intent to materially deceive the FDA and thereby hinder the FDA in carrying out its regulatory responsibilities.

An intent to defraud or mislead individuals can be proven by showing that a defendant knowingly made or caused materially false statements or representations to be made or
02:53 that he intentionally concealed material facts for the purpose of misleading. It is not necessary for you to find that anyone was actually misled or defrauded as long as you find beyond a reasonable doubt that the defendant acted with the intent to mislead or defraud.

In order to prove beyond a reasonable doubt that each defendant distributed an adulterated or misbranded device with the specific intent to defraud or mislead, the government must prove beyond a reasonable doubt that each defendant knew the conduct was unlawful and nevertheless engaged in the conduct of
02:54 the specific intent to disobey or disregard the known legal duties.

The intent to defraud or mislead must be connected to the alleged adulteration or misbranding violation. That is the government must prove beyond a reasonable doubt that the defendant you're considering caused the introduction of

misbranded or adulterated devices into interstate commerce with the intent to defraud or mislead.

To prove intent to defraud or mislead, the government must prove beyond a reasonable doubt that a defendant did not act in good faith but instead acted with a specific intent to defraud or mislead. As I will discuss next, good faith is a complete defense because it is inconsistent with the intent to defraud or mislead. If you find a defendant did not have an intent to defraud or mislead or if you have reasonable doubt as to whether a defendant had an intent to defraud or mislead or whether he acted in good faith, you must find that the government has failed to prove that the defendant acted with the intent to defraud or mislead.

It can be difficult to prove a defendant's state of mind directly, but a defendant's state of mind can be proved indirectly from the surrounding circumstances. This includes things such as what the defendant said or did, how the defendant acted, and any other facts or circumstances in evidence that bear on the defendant's intent.

Good Faith. A defendant's good faith is a complete defense to the portions of adulteration and misbranding charges that require you to find an intent to defraud or mislead. This is the second question relating to misbranding and adulteration on your verdict forms. Good faith is not relevant to the first question where you must determine whether a defendant caused

the introduction of adulterated or misbranded device in interstate commerce. Good faith is also a complete defense to any other charge that requires the government to prove that a defendant acted knowingly and willfully or with an intent to defraud or mislead. This is because if a defendant acted in good faith, then the defendant necessarily lacked the knowledge and willfulness or specific intent to defraud or mislead that the government must prove beyond a reasonable doubt in order to convict the defendant of a count that requires proof of such a state of mind. Again, not all counts charged in this case require proof of such a state of mind, and this instruction applies only to those that do.

A defendant did not act in "good faith" if, even though he honestly held a certain opinion or belief, he also knowingly made false or fraudulent statements, representations or promises to others.

If a person acts either on a belief or an opinion honestly held that his actions were not criminal, that person's actions are not criminal simply because the belief or opinion turns out to be incorrect, inaccurate, or wrong.

A defendant does not bear the burden of proving good faith. Rather, it is the government's burden to prove beyond a reasonable doubt that a defendant did not act in good faith, but instead acted with a specific intent to defraud or mislead with regard to those counts that require proof of the specific

intent to defraud or mislead.

If you find a defendant did not have an intent to defraud or mislead, or if you have reasonable doubt as to whether a defendant had intent to defraud or mislead or whether he acted in good faith, you must find the defendant not guilty of any charge that requires proof of such intent, including wire fraud, which I will discuss shortly.

Now for Count 1. Counts 9 through 18 charge substantive violations of the FDCA, by which I mean actual violations of the FDCA. Count 1, the conspiracy count, by contrast, charges the defendants with conspiring to violate the FDCA. The crime is the agreement to commit the FDCA offenses rather than the actual commission of the offense. To find a defendant guilty of Count 1, you must unanimously find that the government has proved the following three elements beyond a reasonable doubt:

First, that at least two people agreed to violate the Federal Food, Drug and Cosmetic Act in the ways alleged in Count 1;

Second, that the defendant willfully joined the agreement, intending that the charged crime or crimes be committed; and

Third, that at least one co-conspirator committed at least one overt act during the period of the conspiracy in an effort to further the purpose of the conspiracy.

A conspiracy is an agreement, spoken or unspoken. The conspiracy does not have to be a formal agreement or plan in which everyone involved sat down together and worked out all the details.

But the government must prove beyond a reasonable doubt that those who were involved shared a general understanding about the crime. Mere similarity of conduct among various people or the fact that they may have associated with each other or discussed common aims and interests does not necessarily establish proof of the existence of a conspiracy, but you may consider such factors.

To act "willfully" means to act voluntarily and intelligently and with the specific intent that the underlying crime be committed. That is to say, with bad purpose, either to disobey or disregard the law, not to act by ignorance, accident or mistake. The government must prove two types of intent beyond a reasonable doubt to establish that a defendant willfully joined the conspiracy: One, an intent to agree, and two, an intent, whether reasonable or not, that the underlying crime be committed. In considering whether either defendant had the specific intent to commit the underlying FDCA offenses, you should apply the instructions on intent that I previously gave you for each of the underlying offenses. Good faith is a defense to a charge of conspiracy. Mere presence at the scene of a crime is not alone enough, but you may consider it among

other factors. Intent may be inferred from the surrounding circumstances.

Proof that a defendant willfully joined the agreement must be based upon evidence of his own words or actions. You need not find that a defendant agreed specifically to or knew about all of the details of the crime or knew every other co-conspirator or that he participated in each act of the agreement or played a major role. The government must prove beyond a reasonable doubt that he knew the essential features and general aims of the criminal venture. Even if the defendant was not part of the agreement at the very start, he can be found guilty of conspiracy if the government proves that he willfully joined the agreement later. On the other hand, a person who has no knowledge of a conspiracy, but simply happens to act in a way that furthers some object or purpose of the conspiracy, does not thereby become a co-conspirator.

An overt act is any act knowingly committed by one or more of the conspirators in an effort to accomplish some part of the conspiracy. Only one overt act has to be proven. The government is not required to prove that one of these two defendants personally committed or knew about the overt act. It is sufficient if one co-conspirator committed one overt act at some time during the period of the conspiracy.

The government does not have to prove that the conspiracy succeeded or was achieved. The crime of conspiracy

is complete upon the agreement to commit the underlying crime and the commission of one overt act by at least one co-conspirator.

Some of the people who have been involved in these events are not on trial. There is no requirement that all members of a conspiracy be charged and prosecuted, or tried together in one proceeding. Your task is limited to considering the charges contained in the indictment and only as to the defendants before you.

03:01 Finally, the defendants are charged in Counts 5 through 7 with wire fraud. These counts generally allege that the defendants participated in a fraudulent scheme to sell the Stratus for an intended use that was not FDA-cleared or approved and to hide that conduct from the FDA and actual and potential investors and purchasers of Acclarent in order to increase Acclarent's revenues and valuation. To find a defendant guilty of wire fraud, you must find that the government has proved each of the following four elements beyond a reasonable doubt:

03:01 One: That there was a scheme, substantially as charged in the indictment, to defraud or to obtain money or property by means or fraudulent pretenses;

Two: That the scheme to defraud involved the misrepresentation or concealment of a material fact or matter or the scheme to obtain money or property by means of false or

fraudulent pretenses involved a false statement, assertion, half-truth or knowing concealment concerning a material fact or matter;

Three: That the defendant knowingly and willfully participated in the scheme with the intent to defraud; and

Four: That for the purpose of executing the scheme or in furtherance of the scheme, the defendant either caused interstate wire communication, in this case the e-mails charged in the indictment, or it was reasonably foreseeable that for the purpose of executing the scheme or in furtherance of the scheme, the interstate e-mails would be sent, on or about the dates alleged.

A scheme includes any plan, pattern or course of action. The government does not need to prove all of the details alleged in the indictment concerning the precise nature and purpose of the scheme. The government also does not have to prove that the alleged scheme actually succeeded in defrauding or misleading anyone. What must be proven beyond a reasonable doubt is that a defendant knowingly participated in a scheme to defraud that was substantially as charged in the indictment.

The term "defraud" means to deceive another by misrepresenting or concealing a material fact in order to obtain money or property. To defraud, the deceit must cause someone to do that which they would either otherwise not do

which results in deprivation of money or property or causes another to obtain money or property as a result of the fraud. A regulatory clearance does not qualify as money or property for purposes of the wire fraud statute.

The term "false or fraudulent pretenses, representations or promises" means any false statements or assertions (1) that concern a material aspect of the matter in question, (2) that were either known to be untrue when made or unmade with reckless indifference to their truth, and (3) that were made with the intent to defraud.

A false representation can take several forms and can include the following:

1. A knowingly false statement about a material matter that is intended to deceive.

2. A "half-truth," meaning a statement about a material matter that is literally true but is intentionally made deceptive by leaving out important additional information; and

3. An intentional failure to disclose material information that one has a duty to disclose for the purpose of deceiving.

With regards to number 3, generally a failure to disclose alone is not sufficient to establish fraud. A person or a business has a duty to disclose information only if the law imposes such a duty. I instruct you that a person who

submits a written request to the FDA for an order of substantial equivalence, also known as a 510(k) submission, has a duty to disclose in the submission all facts material to the determination of substantial equivalency.

A "material" fact or matter is one that has a natural tendency to influence or is capable of influencing the decision of the decisionmaker to whom it was addressed.

To act "knowingly" means to act voluntarily and intentionally and not because of ignorance, mistake or accident.

An act or failure to act is "willful" if done voluntarily and intentionally, and with the specific intent to do something the law forbids, or with the specific intent to fail to do something the law requires to be done; that is to say, with bad purpose either to disobey or disregard the law. Thus, if a defendant acted in good faith, he cannot be guilty of the crime of wire fraud. The burden to prove intent, as with all other elements of the of the crime, rests with the government.

Again, intent or knowledge may not ordinarily be proven directly because there is no way of directly scrutinizing the ways of the working mind. In determining what a defendant knew or intended at a particular time, you may consider any statements made or acts done or omitted by him and all the facts and circumstances received in evidence that may

aid in your determination of his knowledge or intent. You may infer, but you certainly are not required to infer, that a person intends the natural and probable consequences of acts knowingly done or knowingly omitted. It is entirely up to you, however, to decide what facts are proven by the evidence received during this trial.

An "interstate wire communication" includes an e-mail transmission or other internet communication. The indictment alleges three specific e-mails, one for each of Counts 5, 6 and 7.

Count 5 alleges an e-mail sent on November 13, 2009 from Sales Rep A, Barbara Logan, to Clinic B in Boston. Count 6 alleges an e-mail sent on November 16, 2009 from Sales Rep A, Barbara Logan, to Dr. C in Boston. And Count 7 alleges an e-mail sent on November 19, 2009 from Mr. Fabian to Training Team in Massachusetts.

The wire communication does not itself have to be essential to the scheme but it must have been made for the purpose of carrying it out. There's no requirement that either defendant is personally responsible for the wire communication, that the wire communication itself was fraudulent, or that the use of wire communications facilities in interstate commerce was intended as the specific or exclusive means of accomplishing the alleged fraud. But the government must prove beyond a reasonable doubt that each defendant knew, or could

reasonably have foreseen, that the use of a wire communication, in furtherance or for the purpose of executing the scheme, would follow in the course of the scheme.

The government and defendants have stipulated that the e-mails and other wires identified in Counts 1 and 5 through 7 were interstate wire communications and traveled in interstate commerce.

In Counts 5 through 7 and Counts 9 through 18, each defendant has been charged both as a principal and an aider or abettor. I have already instructed you on the elements of the offenses that need to be proven beyond a reasonable doubt for you to find either defendant guilty as a principal.

A person may also be found guilty of each of those counts if he aided or abetted another in committing the charged offense. To "aid and abet" means intentionally to help someone else commit the charged crime. To establish aiding and abetting, the government must prove beyond a reasonable doubt:

One, that the crime charged was actually committed by someone. This person is called the "principal."

Second, that the defendant took an affirmative act to help or cause the commission of the charged offense; and

Third, that the defendant intended to help or cause the commission of the charged offense.

The second element, the "affirmative act" element, can be satisfied without proof that the defendant participated in

each and every element of the charged offense. It is enough that the defendant assisted in the commission of the charged offense or caused the charged offense to be committed.

The third element, the "intent" element is satisfied if a defendant had advance knowledge of the facts that make the principal's conduct criminal. "Advance knowledge" means knowledge at a time the defendant can opt to walk away.

A general suspicion that an unlawful act may occur or that something criminal is happening is not enough. Mere

03:08 presence at the scene of the charged offense and knowledge that the charged offense is being committed are also not sufficient to constitute aiding and abetting. But you may consider these things among other factors in determining whether the government has met its burden.

I'm going to take a pause and see everyone at sidebar. They have a chance to comment on my instructions, make any corrections. I will be right back. Stand up, stretch. Get your blood flowing. We'll be right back.

* * * * * * * * * * *

03:14 THE COURT: All right. Everybody should now have a copy of the verdict form. When you go back to the jury room, you will actually only have one of those, but I wanted you to each have one in your possession for when I'm giving my final instruction.

It is now time for you to start your deliberations. I

just want to say a few words about your deliberations.

Each of you must decide the case for yourself, but you should do so only after considering all of the evidence and listening to the views of your fellow jurors. You should not hesitate to reconsider your views from time to time and to change them if you are persuaded that that is appropriate. But do not come to a decision simply because other jurors insist that it is right, and do not surrender an honest belief about the weight and effect of the evidence just to reach a verdict.

03:15 Your verdict must be unanimous as to each of the questions I'm going to ask you to answer on the verdict form.

I'm going to ask juror number 1 to serve as foreperson. That's you in the first seat there. Your new number 1, not your old number 1. The foreperson will have the same voice and same vote as other deliberating jurors. The fact that one of you is foreperson does not give that person special status in your deliberations. You are all equal. The foreperson will act, to the extent helpful, as the moderator of the discussion and will serve as the jury's spokesperson. The

03:15 foreperson's most important obligation is to insure that any juror who wishes to be heard on any issue has a full and fair opportunity to be heard by his or her fellow jurors.

If you as a group decide to take a recess during your deliberations, you should stop discussing the case until the recess is over. Do not discuss the case during a recess when

all jurors are present.

If it becomes necessary during your deliberations to communicate with me, you may do so by sending a note through the court officer. No member of the jury should ever attempt to communicate with me, except by such a signed writing. If you do communicate with me, do not tell me in the note how you stand numerically or otherwise, on any issue before you, until after you've reached a verdict. You are not to communicate with anyone but me about the case outside the jury room, and then only in writing. In turn, I will communicate with you only in writing or orally here in open court on anything concerning the case. On matters touching simply on arrangements for your meals, schedule and convenience, you are free to communicate with the court officer or Karen orally rather than in writing.

When you've reached your verdict, your answers will be recorded on what is called the verdict slip or the verdict form. That is simply the written notice of the decision you reach in this case.

I'm going to ask you all to pull out your verdict forms. I'm just going to walk you quickly through it. You will see that the counts in the verdict form are in numerical order, which is not the way I instructed you. You will also see that the defendant -- it is done by defendant but by count or by group of counts. You may consider any count in any order

that you want. You may consider one defendant and then go to the second defendant. You can mix and match. However you want to handle your deliberations is your prerogative. I just organized the verdict form in a way that I thought made sense, but how you conduct your deliberations is entirely up to you.

So the verdict form begins with Count 1, and you see that it asks you to make a decision as to Mr. Facteau on whether you find unanimously that the government has proven beyond a reasonable doubt that he's guilty of that offense. If

03:17 you find him not guilty of that offense, turn to the next page. If you do find him guilty of that offense, Count 1 charges conspiracy to introduce adulterated or misbranded devices. If you find him guilty of the conspiracy, you then have to let us know which theory or both that you have found him guilty based on. That's the second question on that first page. You then go and do the same exercise on the next page for the defendant, Mr. Fabian.

On page 3, Counts 5 through 7 are both there for both defendants and are very straightforward. You then go to Counts

03:18 9 through 13 on page 4, which go to introduction of an adulterated device. That's set up so that it's Mr. Facteau, Counts 9 through 13, and then Mr. Fabian, Counts 9 through 13. Again, any way you want is fine, but that's the way the verdict form was set up. On each of those counts for each defendant, you will find first whether the government has proven beyond a

reasonable doubt that he's guilty of the offense. And then if you find no, you go on to the next count. If you find yes, your second decision is whether or not it was done with the intent to defraud or mislead. That's the same for Counts 9 through 13 for both defendants, which takes us to page 10 of the verdict form, which is counts 14 through 18. And it's set up very much in the same way, first off, all those counts for Mr. Facteau and then all those counts for Mr. Fabian.

For the misbranding counts, introduction of misbranded
03:19 device, you first make a decision about whether or not you find the government has proven beyond a reasonable doubt that the defendant is guilty of the offense. If you find him not guilty, you go on to the next count. If you find him guilty, then you have to tell him which of the three misbranding theories you find him guilty of, and that decision must be unanimous.

I guess, just to go back to Count 1 for a second, same thing. When you're telling us which theory or theories you found proved, you have to be unanimous on that decision as
03:19 well. Those are the misbranding counts.

Then the very last page of the verdict form just requires your foreperson to sign and date it and represent that those are the unanimous findings of the jury.

After you've reached a unanimous agreement on the form, your foreperson will fill in the verdict form, sign and

date it, and tell the court officer outside your door that you are ready to return to the courtroom. After you return to the courtroom, your foreperson will deliver the completed verdict form as directed in open court.

Anything else from anybody that we haven't already been heard on before I send them out? Okay.

(Jury exits, 3:19 p.m.)

CERTIFICATE OF OFFICIAL REPORTER

I, Kelly Mortellite, Registered Merit Reporter and Certified Realtime Reporter, in and for the United States District Court for the District of Massachusetts, do hereby certify that pursuant to Section 753, Title 28, United States Code that the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

Dated this 20th day of July, 2016.

/s/ Kelly Mortellite

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Kelly Mortellite, RMR, CRR

Official Court Reporter

10:33